

## Onconova Therapeutics, Inc. (Nasdaq CM: ONTX, Target Price: \$5.00)

We initiate coverage on Onconova Therapeutics, Inc. (Nasdaq CM: ONTX, "Onconova") with a price target of \$5.00. Onconova is a Phase 3 clinical-stage biopharmaceutical company focused on developing novel therapeutics to treat cancer. With headquarters in Newtown, PA, Onconova was founded in 1998 and became a public company through an initial public offering in 2013. Onconova is initially focused on developing therapeutics for cancer patients with unmet needs, leveraging a proprietary chemistry that seeks to target specific cellular pathways linked to cancer cells, while causing minimal damage to healthy cells. Its lead candidate, **rigosertib**, is in advanced clinical trials investigating its use as treatment for myelodysplastic syndromes (MDS), a rare group of cancers affecting bone marrow blood cells, which the company believes may also have therapeutic potential for acute myeloid leukemia (AML) in the future.

### INVESTMENT HIGHLIGHTS

#### Several potential catalysts ahead for Onconova enters 2017 funded to advance two Phase 3 clinical trials

We see several potential attributes for Onconova ahead in 2017. The company enters the year with a strong cash position, with \$25.8mn of cash on its balance sheet at the end of 3Q16. Management expects this to be sufficient to fund the advancement of its ongoing INSPIRE Phase 3 clinical trials for rigosertib in IV-administered formulation as a second line therapy for higher risk MDS (HR-MDS). Also, in 2017 Onconova plans to advance the oral formulation of rigosertib to Phase 3 as a potential first line combination therapy for HR-MDS. With two Phase 3 trials in 2017, we would expect a steady stream of clinical updates throughout the year, in addition to business development activities for the company's non-core candidates.

#### Onconova enters 2017 with two Phase 3 clinical trials

We find ourselves enthused for several key clinical milestones ahead of Onconova. The company has made significant progress since disappointing trial results in 2014, and now boasts a pipeline highlighted by two Phase 3 clinical trials for its lead candidate, rigosertib. The trials are investigating rigosertib as a potential therapeutic for higher risk myelodysplastic syndromes (HR-MDS), a rare group of cancers affecting bone marrow blood cells, for which the FDA has not approved a new drug since 2006. Onconova's lead candidate has a differentiated method of action for treating HR-MDS, by targeting the RAS pathways, which play a key role in regulating cell growth and malignant transformation, and which management believes may have therapeutic potential for other indications, such as AML, in the future. With successful efficacy data, a case could be made for rigosertib as a second line treatment for HR-MDS patients who did not respond to hypomethylating agents (HMA), or as a first line therapy in combination with HMAs. Onconova management expects to report interim data during mid-2017 for its ongoing INSPIRE Phase 3 trial, with top-line data expected in 2018. The company also plans to disclose trial protocol for its Phase 3 combination trial for the oral formulation of rigosertib in 1H17.

#### Initiate coverage with a price target of \$5.00

We initiate coverage of Onconova with a price target of \$5.00. The company represents an intriguing, speculative company in the biopharmaceutical industry, with two Phase 3 clinical trials ahead for its lead product in 2017 and \$25.8mn in cash and investments on its balance sheet as of 3Q16.

#### Stock Details (1/5/2017)

Nasdaq CM:	ONTX
Sector / Industry	Healthcare / Biopharmaceuticals
<b>Price target</b>	<b>\$5.00</b>
Recent share price	\$2.31
Basic Shares o/s (mn)	6.8
Market cap (in \$mn)	15.6
52-week high/low	\$10.30 / 2.11

#### Key Financials (\$mn unless specified)

	FY15	FY16E	FY17E
Revenues	11.5	5.4	8.0
EBITDA	(23.8)	(22.4)	(23.2)
EBIT	(24.0)	(22.5)	(23.3)
Net income	(24.0)	(22.5)	(23.3)
EPS (\$)	(10.54)	(3.21)	(1.81)

Source: SeeThruEquity Research

#### Key Ratios

	FY15	FY16E	FY17E
Gross margin (%)	100.0	100.0	100.0
Operating Margin (%)	(209.3)	(414.7)	(291.3)
EBITDA margin (%)	(208.0)	(412.9)	(290.1)
Net margin (%)	(209.4)	(414.6)	(291.3)
P / Revenue (x)	1.4	2.9	2.0
EV/Revenue (x)	NM	NM	NM

Source: SeeThruEquity Research

#### Share Price Performance (\$)



Source: Bloomberg

## SUMMARY TABLE

Figure 1. Summary Table (Pricing data as of January 5, 2017)

Share data		Balance Sheet data (3Q16)		Key personnel:	
Recent price:	\$2.31	Total assets:	28.1mn	CEO	Dr. Ramesh Kumar Ph.D.
Price target:	\$5.00	Total debt*:	0.0mn	Founder, Lead Scientific Advisor	Dr. E. Premkumar Reddy Ph.D.
52-week range:	2.11 - 10.30	Equity:	10.0mn	Chief Medical Officer	Dr. Steven M. Fruchtmann M.D.
Average volume*:	85,170	W/C:	18.9mn	CFO	Mark Patrick Guerin
Market cap*:	\$15.6mn	ROE:	-155%		
Book value/share:	\$1.48	ROA:	-30%		
Cash/ basic share	\$3.81	Current ratio:	3.1		
Dividend yield:	0.00%	Asset turnover:	NM		
Risk profile:	High / Speculative	Debt/Cap:	0.0%		

\* 30-day average volume (number of shares)

Estimates					Valuation	
FY December	Rev (\$mn)	EBITDA (\$mn)	EPS (\$)	P/Rev (x)	EV/Rev (x)	P/E (x)
2015	11.5	(23.8)	(10.54)	1.4x	NM	NM
2016E	5.4	(22.4)	(3.21)	2.9x	NM	NM
2017E	8.0	(23.2)	(1.81)	2.0x	NM	NM
2018E	15.0	(17.2)	(1.12)	1.0x	NM	NM
2019E	18.8	(0.6)	(0.07)	0.8x	NM	NM

Source: SeeThruEquity Research

## INVESTMENT THESIS

We initiate coverage on Onconova Therapeutics, Inc. (Nasdaq CM: ONTX, "Onconova") with a price target of \$5.00. Onconova is a Phase 3 clinical-stage biopharmaceutical company focused on developing novel therapeutics to treat cancer. With headquarters in Newtown, PA, Onconova was founded in 1998 and became a public company through an initial public offering on the Nasdaq in 2013. Onconova is initially focused on developing therapeutics for cancer patients with unmet needs. The company employs a proprietary chemistry that seeks to target specific RAS cellular pathways, which have been linked to cancer cells, while causing minimal damage to healthy cells. Its lead candidate, **rigosertib**, is in advanced clinical trials investigating its use as treatment for **myelodysplastic syndromes (MDS)**, a rare group of cancers affecting bone marrow blood cells. Management also believes rigosertib has the potential to be developed as a therapeutic for other indications, such as AML, in the future. The company's ongoing Phase 3 INSPIRE trial is investigating IV-administered rigosertib as a second line treatment for higher risk MDS (HR-MDS). Onconova has also announced that it will commence a new Phase 3 combination trial with an oral formulation of rigosertib. The combination of these trials advancing concurrently in 2017 should provide a steady flow of clinical events, providing insight into the company's prospects. Additionally, Onconova enters 2017 with funding a cash position of \$25.8mn and no financial debt as of the end of 3Q16, leaving it with what management has stated is sufficient funding to execute on its Phase 3 clinical plans for 2017.

### Clinical Pipeline led by Phase 3 programs for lead candidate rigosertib

Onconova is a Phase 3 clinical-stage biopharmaceutical company developing therapeutics for unmet needs in cancer, beginning with myelodysplastic syndromes (MDS). Onconova has two advanced programs for MDS, its ongoing Phase 3 INSPIRE clinical trial of an intravenous formulation of **rigosertib**, as well as its combination program for an oral formulation of rigosertib, which is expected to commence a Phase 3 trial in 2017, following recent Phase 2 results and what management described as a favorable meeting with the FDA. The company has secured patent protection for rigosertib through 2026 (composition), and 2028 (combination), and rigosertib has received an Orphan Drug Designation for MDS in the United States. Importantly, rigosertib has extensive safety data from administration to over 1,000 patients (including both oral and IV) in the United States, representing an extensive clinical trial database.

We believe Onconova is rightfully focused on advancing these two clinical programs: the oral and IV formulation of its lead drug candidate rigosertib. The company has engaged Symbio as a strategic partner to develop and market the drug in Japan and Korea, and management has indicated that it will seek advantageous partnership opportunities in larger markets such as the US and Europe over the next 18 months as the programs advance. Onconova also has three additional early-stage programs, comprising two Phase 1 stage programs and one pre-IND program, as illustrated in the following pipeline graphic. Management has publicly stated its intent to pursue business development opportunities for these programs, in order to allow the company to focus on the core rigosertib programs.

Figure 4. Clinical Pipeline

Program	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Method of Action
Single-agent IV rigosertib	2 <sup>nd</sup> - line HR-MDS	INSPIRE Pivotal Trial				Ras Signaling
Oral rigosertib + azacitidine	1 <sup>st</sup> - line HR-MDS	09 - 08 Phase 2 Trial				
IV Briciclib	Solid tumors	Dose-escalation Phase 1 Trial				elF4E targeting
Recilisib	ARS*	Non-Human Primate Efficacy				Targeting radiation-induced apoptosis
ON 123300	CDK4/6 overactive tumors	Pre-IND Stage				CDK4/6 Targeting

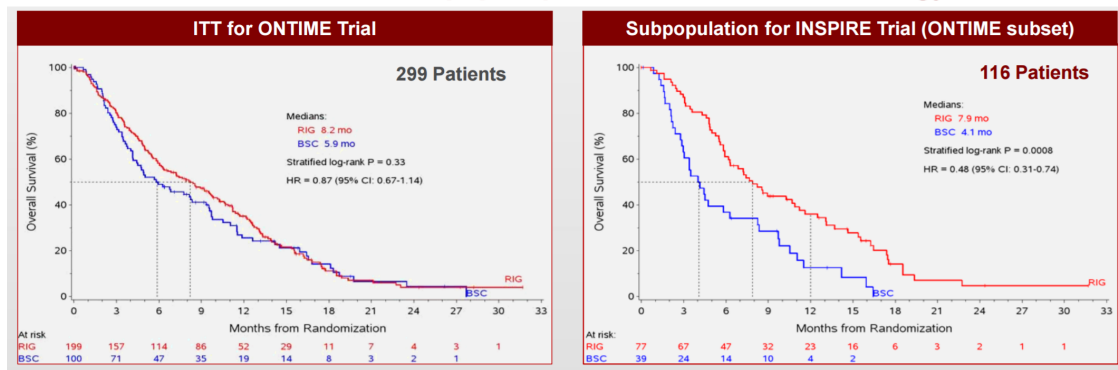
Source: Company investor materials

### Ongoing Phase 3 INSPIRE trial for second line HR-MDS, commencing additional Phase 3 trial in 2017

Onconova is likely to have numerous clinical events over the next 12-18 months as the company advances its programs investigating the use of rigosertib for MDS. The company's most advanced program is its ongoing, **Phase 3 INSPIRE trial**, in which the intravenous (IV) formulation of rigosertib is being administered to higher risk MDS patients (HR-MDS). There are only three approved drugs for MDS in the United States,

and the most recent of these was approved by the FDA more ten years ago. The INSPIRE trial is seeking to show that IV-administered rigosertib has the potential to be an effective life-extending second line therapy for MDS patients who did not respond to hypomethylating agents (HMA), the current standard of care. Currently the life expectancy of these patients is just 4-6 months. Data from the company's 2014 Phase 3 ONTIME trial suggested that life extension was possible from rigosertib IV treatment for this subpopulation, which suggests potential for its use as a second line therapy for HR-MDS patients failing to respond to HMAs.

### Data from ONTIME paper\* published in *Lancet Oncology*



The INSPIRE trial is a global trial, which enrolled its first patient in December 2015 at MD Anderson in the US, with initial patients in Europe and Japan in months thereafter. The trial is planned to include 225 patients at 171 prospective sites in North America, Europe, Australia and Asia. Onconova management expects to report interim data during mid-2017, with top-line data expected in 2018.

### Oral formulation Phase 2 results presented at ASH; support Phase 3 combination trial

As for its oral formulation administered program for rigosertib, Onconova recently completed a Phase 2 clinical trial of rigosertib and azacitidine in sequence for HR-MDS patients, with a goal of improving on the standard of care for HR-MDS patients through combination therapy.

The company presented supportive data for this approach at the American Society of Hematology (ASH) Annual Meeting in San Diego, CA, in December 2016. Lead Lewis R. Silverman, M.D. of Mt. Sinai noted that the complete remission rate amongst HMA-naïve HR-MDS patients was higher with faster responses with the oral rigosertib combination, versus single-agent azacitidine, without substantially changing the adverse event profile. Specifically, at the time data was compiled for the presentation, 33 HR-MDS patients were evaluable for efficacy assessment per 2006 IWG criteria. Of this group, 25 of the 33 patients, or 76%, responded to the combination therapy, including 85% of HMA-naïve patients and 62% of HMA-resistant patients, with seven patients displaying complete remission. Notably the complete remission (CR) rate was reported to be 35% in front line and 8% in second line patients.

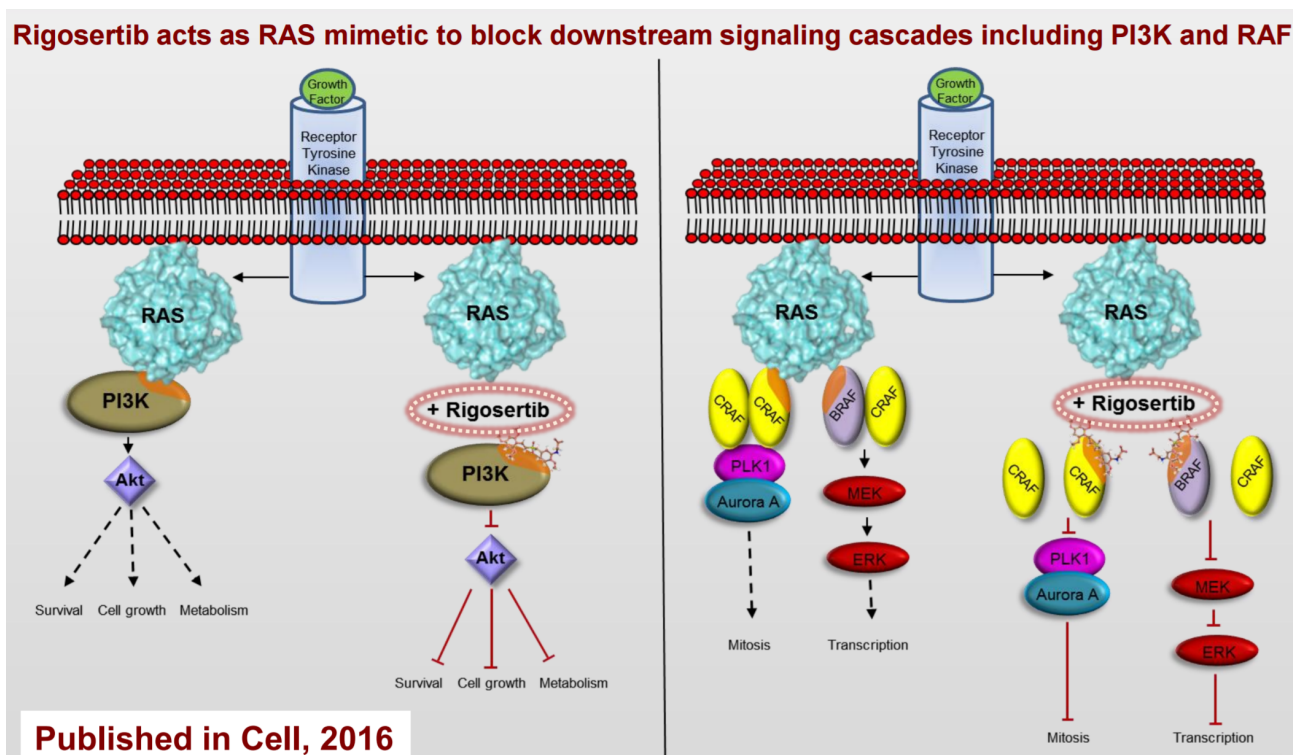
Onconova has announced plans to initiate a Phase 3 clinical trial for oral rigosertib in combination with injectable azacitidine in 2017 following an End of Phase 2 (EOP2) meeting with the FDA, which occurred in September 2016. Management expects to announce trial protocol during 1H2017, with a goal of commencing the Phase 3 trial in the second of 2017. Importantly, during its meeting with the FDA, Onconova management was able to determine that the expected endpoint of the upcoming combination Phase 3 trial will be related to response, rather than overall survival rate – likely reducing the cost and timing of the pivotal trial.

### Rigosertib's mechanism of action targeting RAS offers possibilities for other indications

Rigosertib is a small molecule inhibitor of cellular signaling characterized by a unique mechanism of action directed against the RAS pathways. RAS proteins control cell signaling pathways, which are thought to be

key regulators of cell growth and differentiation. Rigosertib has been shown in prior trials to interfere with RAS signaling involving the RAS binding domain, as illustrated in the following graphic, provided by the company.

Figure 5. Rigosertib Mechanism of action directed against RAS pathways



Source: Company investor materials

While we expect Onconova to remain focused on its programs for MDS, it is worth noting that rigosertib's mechanism of action could also have potential applications for additional cancers. There are multiple signaling pathways in the cell, which involve a common protein, RAS. Indeed, Onconova estimates that more than a third of all cancers have implications of RAS, which should support further investigations into other applications of rigosertib's applicability as an RAS antagonist. We would expect to learn more about the company's plans for additional indications in 2017-2018; however, would note that related indications that may be considered could include acute myelogenous leukemia (AML), and other bone marrow related indications, such as myeloproliferative neoplasms (MPN), as well as paroxysmal nocturnal hemoglobinuria (PNH), among others.



## COMPETITIVE LANDSCAPE

We see Onconova as pursuing an opportunistic area in a very competitive industry. Onconova is a late-clinical stage company competing in the biopharmaceutical industry. The pharmaceutical industry is a large and highly competitive market, which is characterized by innovation, high barriers to entry, as well as extensive and costly regulation. Further, the industry is dominated by several large multinational corporations, which benefit from access to deep financial resources, established sales and distribution networks, as well as regulatory experience and influence.

Onconova seeks to compete through a focused differentiation strategy for treating cancer, an area which is likely to attract increased competition due to its growing prevalence. The company's lead product, rigosertib, has a novel mechanism of action for the potential treatment of cancer by disrupting RAS pathways.. Onconova is initially focused on higher-risk myelodysplastic syndromes (HR-MDS), though we expect the company to seek to investigate rigosertib's therapeutic potential to address overlapping indications, such as AML, in the future. Onconova's lead candidate, rigosertib, is supported by intellectual property protection through 2026-2028. Onconova has received an Orphan Drug Designation from the FDA for rigosertib for HR-MDS in the US; rigosertib has also received orphan designations in Europe and Japan.

MDS represents an indication with significant unmet needs. The prevalence of MDS at approximately 61,690 cases in the United States, with 18,000 incidences of per year. Despite the number of new MDS patients each year, there have been no new FDA-approved treatments for HR-MDS since 2006, and the current standard of care consists primarily of hypomethylating agents (HMAs) Vidaza and Dacogen. HMAs only work for a subset of patients, and are largely not curative, in addition to carrying side effects. HR-MDS patients who fail to respond to HMAs typically have a life expectance of four to six months, with no FDA-approved second line treatments.

In the area of MDS, Onconova management sees competition from several clinical trials, which intend to use immunotherapy or chemotherapy treatment to treat HR-MDS. Management specifically mentioned Eisai, Celgene Corporation, Cell Therapeutics, Inc., Cyclacel Pharmaceuticals, Astex / Otsuka, Array BioPharma, and Acceleron Pharma as competitors. We expect the company to advance development in its programs while also seeking to form strategic partnerships with large pharmaceutical corporations to support commercialization.

## FINANCIALS AND FUTURE OUTLOOK

### Key Assumptions

We note that Onconova is a clinical-stage company, whose lead clinical programs have not been cleared for sale by the FDA in the United States, or another regulatory body elsewhere. The regulatory approval process is inherently uncertain, and even Phase 3 candidates have a measurable risk of not meeting clinical endpoints. Although this analysis employs a probability discount factor, which attempts to account for the uncertainty in the regulatory approval process, readers of this analysis should be aware that drug candidates that are not approved by the FDA cannot be marketed in the United States, and therefore a negative FDA decision would have a materially negative impact on the prospects for the company.

We have assumed that Onconova pursues a partnership based approach to commercialization. We expect the company to fund its development through Phase 3 data, and assume that the company will be successful in business development activities. Specifically, we have assumed that Onconova will be able to strike strategic licensing deals with pharmaceutical partners in North America and Europe, comprising an upfront fee, milestone payments, and a double-digit royalty rate. The company has stated publicly that it is also pursuing business development activities for non-core programs, which, if successful, would help support development in MDS.

We assumed IV-administered rigosertib will be approved by the end of 2018, with 2019 being the first year of commercial operations. Our model assumes the company is able to strike at least one licensing deal by the end of 2017, following interim data from its ongoing Phase 3 trial. For the oral combination pivotal trial of rigosertib and azacitidine, we assumed approval in 2019 with 2020 being the first year of commercial operations. As noted above, although these are Phase 3 trials, there remains uncertainty inherent in the approval process, as well as the company's ability to execute business development initiatives to strike licensing deals. Reflecting this, valuation from our model applies a probability factor of 0.7x, as well as a discount rate of 16.3%.

### Balance Sheet & Financial Liquidity

We see the balance sheet as a key item to watch for small cap healthcare companies given that they typically are unable to generate free cash flow from operations until products are approved / cleared by the FDA, or they have shown enough evidence in clinical trials to attract the attention of a larger industry player to form a licensing agreement. While Onconova has a history of operating losses and will not generate free cash flow in 2017 or 2018, in our view, without a strategic licensing agreement, the company does appear to have sufficient funding to meet its operating plan and clinical objectives for 2017E, which should include interim data on its lead Phase 3 clinical program for rigosertib for MDS, as well as a pivotal Phase 2 combination trial.

Onconova completed an over-subscribed rights offering in July 2016, resulting in an improved balance sheet. At the end of 3Q16, Onconova had cash and marketable securities of \$25.8mn, and positive shareholders' equity of \$10.0mn. Management stated that it believes it has sufficient capital to fund its clinical program through the end of 2017. We have assumed Onconova will seek to raise additional capital of at least \$30mn to fund 2018-2019 initiatives, and note that the company believes it will be in a position for Phase 3 top line data in 2018E.

## VALUATION

We valued Onconova using a discounted cash flow (“DCF”) model arrive at a price target of \$5.00. We felt that this method was more appropriate than a comparable company valuation given that Onconova does not have approved FDA products, and therefore a comparison based on fundamentals would not provide meaningful input to determining a price target. We also included a table of competitors in the industry and peer companies developing therapeutics for MDS and/or AML, for informational purposes.

### DCF

The following DCF valuation of Onconova runs through 2027E. Overall, our forecast assumes that Onconova pursues a partnership-based commercialization strategy, as described in more detail in the Financials & Future Outlook portion of this report. We assumed that Onconova and a strategic partner are able to launch the initial candidate IV-administered rigosertib, in 2019, and that its orally administered formulation launches in 2020.

We discounted cash flows at a weighted average cost of capital of 16.3%. We also applied a probability factor of 0.7x, to reflect risk that its candidates are not cleared by the FDA. Even for Phase 3 candidates, the FDA approval process is one with inherent uncertainty. Finally, we assumed a terminal growth rate of 5% at the end of FY2027E to arrive at \$5.37, as shown below.

\$' 000	FY17E	FY18E	FY19E	FY20E	FY21E	FY22E	FY23E	FY24E	FY25E	FY26E	FY27E
EBIT	(23,300)	(17,300)	(1,068)	(1,368)	5,245	7,688	12,455	19,719	24,909	17,636	18,157
Less: Tax	0	0	0	0	0	0	0	0	0	0	0
<b>NOPLAT</b>	<b>(23,300)</b>	<b>(17,300)</b>	<b>(1,068)</b>	<b>(1,368)</b>	<b>5,245</b>	<b>7,688</b>	<b>12,455</b>	<b>19,719</b>	<b>24,909</b>	<b>17,636</b>	<b>18,157</b>
Changes in working capital	(1,187)	(1,399)	2,753	(1,698)	144	155	729	238	745	281	300
Depreciation & Amortization	96	96	445	616	875	1,083	1,252	1,391	1,506	1,604	1,689
Capex	(400)	(900)	(918)	(1,200)	(1,755)	(1,790)	(1,826)	(1,862)	(1,900)	(1,938)	(1,976)
<b>FCFF</b>	<b>(24,791)</b>	<b>(19,503)</b>	<b>1,213</b>	<b>(3,649)</b>	<b>4,509</b>	<b>7,136</b>	<b>12,610</b>	<b>19,485</b>	<b>25,261</b>	<b>17,583</b>	<b>18,170</b>
Discount factor	0.86	0.74	0.64	0.55	0.47	0.40	0.35	0.30	0.26	0.22	0.19
Probability Factor	1.00	0.70	0.70	0.70	0.70	0.70	0.70	0.70	0.70	0.70	0.70
PV of FCFE	(21,308)	(10,089)	539	(1,396)	1,483	2,018	3,066	4,074	4,541	2,718	2,415
Sum of PV of FCFE											(11,939)
Terminal cash flow											168,832
PV of terminal cash flow											22,439
<b>Enterprise value</b>											<b>10,499</b>
Less: Debt											0
Add: Cash											25,780
<b>Equity value</b>											<b>36,279</b>
Basic Outstanding shares (mn)											6.8
<b>Fair value per share (\$)</b>											<b>5.37</b>



Summary conclusions		Key assumptions	
DCF FV (\$ per share)	5.37	Beta	2.0
Recent price (\$ per share)	2.33	Cost of equity	16.3%
Upside (downside)	130.3%	Cost of debt (post tax)	9.1%
WACC	16.3%	Terminal Growth Rate	5.0%

Source: SeeThruEquity Research, Cash as of 3Q16

Figure 7. Sensitivity of Valuation – WACC vs. Terminal Growth Rate

		WACC (%)				
Terminal growth rate (%)		15.3%	15.8%	16.3%	16.8%	17.3%
	4.00%	5.83	5.43	5.07	4.74	4.44
	4.50%	6.01	5.59	5.21	4.87	4.55
	5.00%	6.22	5.77	5.37	5.00	4.67
	5.50%	6.44	5.96	5.54	5.15	4.81
	6.00%	6.69	6.18	5.72	5.32	4.95
	6.50%	6.97	6.42	5.93	5.49	5.11

Source: SeeThruEquity Research

### Peer Group Analysis

We also evaluated Onconova by using a relative valuation analysis with peer companies in the biopharmaceutical sector. As stated earlier in this report, we did not use this analysis to determine the price target. Onconova does not have products approved for sale by the FDA, and therefore a classical fundamental analysis is less meaningful to determining the price target. In our view, the key determining valuation catalyst for Onconova will be whether its Phase 3 trials can show efficacy, creating a demand for larger pharmaceuticals to partner with the company to refresh treatment options for MDS patients. Nevertheless, we have included a table of comparable companies for informative purposes, included below.

Figure 6. Comparable Valuation \*

Company	Stock Ticker	Mkt cap (\$ mn)	Area of Focus	EV/ Sales (x)	
				TY	NY
Acceleron	XLRN	1,120	Protein therapeutics for cancer & rare disease	35.2x	28.0x
Cyclacel Pharma	CYCC	12	Targeted small molecule anticancer technologies	12.7x	NM
GlycoMimetics	GLYC	144	AML; anti-cancer attacking glycoside	103.3x	4.8x
Array Pharma	ARRY	1,474	Anti-cancer small molecule & rare genetic disease	10.8x	10.3x
Celgene Corporation	CELG	90,404	Global therapeutics for cancer and anti-inflammatory disease	8.7x	7.4x
Vascular Biogenics	CTIC	124	targeted therapies for blood related cancers	1.7x	5.0x
Celldex Therapeutics	CLDX	468	Glioblastoma; immunotherapy	34.2x	12.0x
<b>Average</b>				<b>29.5x</b>	<b>11.3x</b>
Onconova	ONTX	16	Anti-cancer technology focused on RAS pathways	NM	NM
<i>Premium (discount)</i>		<i>NM</i>		<i>NM</i>	<i>NM</i>

Source: Bloomberg, SeeThruEquity Research, data as of December 2016

## RISK CONSIDERATIONS

### Financial resources

Although Onconova ended 3Q16 with \$25.8mn of cash and investments on its balance sheet the company does not generate free cash flow and will be unable to generate substantial free cash flows until / if its products are approved for commercialization by regulatory bodies (the FDA in the United States). Obtaining regulatory approval for a new drug requires costly clinical trials, and we have assumed that Onconova will require a minimum of an additional \$30mn in new capital before it is able to generate cash flows from commercial products, either marketed by the company, or – more likely – through a licensing partnership. We expect the company to seek to raise capital throughout 2017-2019, in order to fund operations and advance clinical trials.

### Innovation / Technology Risk

The pharmaceutical market is subject to change and innovation, and Onconova is exposed to risk that new products are introduced, which are better able to treat MDS and other potential future indications. Additionally, there are many companies seeking to address the relationship between RAS and cancer, and the company could be exposed to risk from innovations seeking to address other cancerous indications, which could have applicability for MDS.

### Competition

The market for developing and commercializing biopharmaceuticals is competitive, requires significant capital investment, and is subject to with a high degree of regulation. Further, the industry includes many well-established multi-national corporations, which have access to more advanced research and development facilities, more established brand recognition and sales distribution, and substantially more capital. Onconova has specifically identified Celgene as a close competitor for MDS.

### Regulation

Onconova operates in a highly regulated industry, and will be unable to market its products in the United States without receiving clearance from the Food & Drug Administration (FDA). Outcomes of the FDA approval process are inherently uncertain and often have a material impact on security prices.

### Risk related to prior ONTIME trial

Readers of this analysis should be aware that Onconova completed a Phase 3 trial for IV-administered rigosertib as a single agent for HR-MDS, and the company failed to meet its endpoint, despite showing improvements in overall survival and in various pre-specified subgroups of HR-MDS. The company has refined its target patient population for its ongoing INSPIRE trial to investigate its potential as a second line treatment for HR-MDS patients who were unresponsive to HMA therapy.

## Management Team

### **Ramesh Kumar, Ph.D. President & CEO**

Dr. Kumar co-founded Onconova in 1998. He received his Ph.D. in Molecular Biology from the University of Illinois, Chicago, and trained at the National Cancer Institute. He has held positions in R&D or management at Princeton University, Bristol-Myers Squibb, DNX (later Nextran, a subsidiary of Baxter) and Kimeragen (later Valigen), where he was President of the Genomics and Transgenics Division. Dr. Kumar has more than 50 publications spanning molecular oncology, transgenic animals, gene therapy and recombination. He is an inventor in eight U.S. patents and many patent applications. He co-edited the 1993 book "Molecular Basis of Human Cancer."

### **E. Premkumar Reddy, Ph.D, Founder, Lead Scientific Advisor**

Dr. Reddy is a renowned scientist with a specific interest in molecular oncology. He is a Professor in the Department of Oncological Sciences & Department of Structural & Chemical Biology at the Mount Sinai School of Medicine in New York. Dr. Reddy is a pioneer in the understanding of the molecular basis of cancer and the development of novel anti-cancer strategies. He is the author of more than 200 publications and several dozen patent applications. Dr. Reddy founded Onconova Therapeutics in 1998. He was a co-editor of the international journal of cancer research, *Oncogene*, published by Nature Publishing Group. Among Dr. Reddy's many accomplishments are the co-invention of a diagnostic procedure used in HIV AIDS testing and the novel drug candidates being developed by Onconova.

### **Mark Guerin, CFO**

Mr. Guerin joined Onconova Therapeutics in September 2013 to augment the financial reporting, forecasting, and internal controls capabilities of the company following the IPO in July 2013. Prior to joining Onconova, Mr. Guerin worked as an interim senior finance & accounting executive facilitating the post-acquisition integration activities of newly-acquired private equity portfolio companies. Previously, Mr. Guerin was the VP Finance & CFO of Cardiokine, Inc. through that company's filing of a New Drug Application and the sale of the company. Prior to joining Cardiokine, Mr. Guerin was Director, Financial Reporting & Internal Controls at Barrier Therapeutics, Inc. during Barrier's IPO and follow-on offering. Mr. Guerin started his career at Coopers & Lybrand in Philadelphia. He received his bachelor's degree in Accounting from DeSales University and has earned the CPA, CMA, and CFM professional certifications.

### **Steven M. Fruchtman, M.D., Chief Medical Officer**

Dr. Fruchtman joined Onconova in January, 2015. He has extensive experience in large and small biopharmaceutical companies and has led successful clinical development programs while serving in senior positions at Ortho Biotech Products, Novartis, Allos Therapeutics, Spectrum Pharmaceuticals and Syndax Pharmaceuticals. Earlier, Dr. Fruchtman was on the faculty of the Mount Sinai School of Medicine and the Director of the Stem Cell Transplantation and Myeloproliferative Disorder Programs at Mount Sinai Hospital in New York City. He is an author of more than 170 lectures, presentations, books, chapters, and abstracts and serves as an external reviewer for multiple medical journals. Dr. Fruchtman received his medical degree from New York Medical College with the distinction of membership in the Alpha Omega Alpha honorary medical fraternity.

### **Manoj Maniar, Ph.D. Senior Vice President, Product Development**

Dr. Maniar received his B.S. in Pharmacy from Bombay College of Pharmacy and his Ph.D. in Pharmaceutics from the University of Connecticut. He has led the development and commercialization of several pharmaceutical products and medical devices during his career. Prior to joining Onconova, Dr. Maniar was with SRI International, where he served as Senior Director, Formulations and Drug Delivery. He has authored more than 100 patents, publications, and presentations in the field of pharmaceutical sciences.

## FINANCIAL SUMMARY

Figure 7. Income Statement

Figures in \$mn unless specified	FY15	FY16E	FY17E	FY18E	FY19E	FY20E
<b>Revenue</b>	<b>11.5</b>	<b>5.4</b>	<b>8.0</b>	<b>15.0</b>	<b>18.8</b>	<b>19.5</b>
YoY growth		(52.6%)	47.5%	87.5%	25.4%	3.7%
Cost of sales	0.0	0.0	0.0	0.3	0.4	0.4
<b>Gross Profit</b>	<b>11.5</b>	<b>5.4</b>	<b>8.0</b>	<b>14.7</b>	<b>18.4</b>	<b>19.1</b>
Margin	100.0%	100.0%	100.0%	98.0%	98.0%	98.0%
Operating expenses	35.4	27.9	31.3	32.0	19.5	20.5
EBIT	(24.0)	(22.5)	(23.3)	(17.3)	(1.1)	(1.4)
Margin	(209.4%)	(414.7%)	(291.3%)	(115.3%)	(5.7%)	(7.0%)
<b>EBITDA</b>	<b>(23.8)</b>	<b>(22.4)</b>	<b>(23.2)</b>	<b>(17.2)</b>	<b>(0.6)</b>	<b>(0.8)</b>
Margin	(208.1%)	(412.9%)	(290.1%)	(114.7%)	(3.3%)	(3.9%)
Other income/ (expense)	(0.0)	0.0	0.0	0.0	0.0	0.0
Profit before tax	(23.9)	(22.5)	(23.3)	(17.3)	(1.1)	(1.4)
Tax	0.0	0.0	0.0	0.0	0.0	0.0
<b>Net income to Common</b>	<b>(23.9)</b>	<b>(22.5)</b>	<b>(23.3)</b>	<b>(17.3)</b>	<b>(1.1)</b>	<b>(1.4)</b>
Margin	(208.4%)	(414.6%)	(291.3%)	(115.3%)	(5.7%)	(7.0%)
<b>EPS (per share)</b>	<b>(10.54)</b>	<b>(3.21)</b>	<b>(1.81)</b>	<b>(1.12)</b>	<b>(0.07)</b>	<b>(0.09)</b>

Source: SeeThruEquity Research.

Figure 8. Balance Sheet

Figures in \$mn, unless specified	FY15	FY16E	FY17E	FY18E	FY19E	FY20E
Current assets	23.2	23.4	22.3	19.1	25.7	30.2
Other assets	0.2	0.2	0.5	1.1	1.6	2.2
<b>Total assets</b>	<b>23.4</b>	<b>23.6</b>	<b>22.8</b>	<b>20.3</b>	<b>27.3</b>	<b>32.4</b>
Current liabilities	7.6	9.0	3.3	4.6	9.0	11.7
Other liabilities	5.0	9.1	9.1	9.2	9.3	9.4
Shareholders' equity	10.8	5.5	5.5	6.5	9.1	11.3
<b>Total liab and shareholder equity</b>	<b>23.4</b>	<b>23.6</b>	<b>17.9</b>	<b>20.3</b>	<b>27.3</b>	<b>32.4</b>

Source: SeeThruEquity Research

Figure 9. Cash Flow Statement

Figures in \$mn, unless specified	FY15	FY16E	FY17E	FY18E	FY19E	FY20E
Cash from operating activities	(31.2)	(18.8)	(21.0)	(15.1)	5.7	1.2
Cash from investing activities	0.0	0.0	(0.4)	(0.9)	(0.9)	(1.2)
Cash from financing activities	7.5	17.4	20.0	10.0	0.0	0.0
<b>Net inc/(dec) in cash</b>	<b>(23.8)</b>	<b>(1.4)</b>	<b>(1.4)</b>	<b>(6.0)</b>	<b>4.8</b>	<b>(0.0)</b>
Cash at beginning of the year	43.6	19.8	18.4	17.0	11.0	15.8
<b>Cash at the end of the year</b>	<b>19.8</b>	<b>18.4</b>	<b>17.0</b>	<b>11.0</b>	<b>15.8</b>	<b>15.8</b>

Source: SeeThruEquity Research

## About Onconova Therapeutics, Inc.

Onconova Therapeutics is a Phase 3 clinical-stage biopharmaceutical company focused on discovering and developing novel products to treat cancer. Onconova's clinical and pre-clinical stage drug development candidates are derived from its extensive chemical library and are designed to work against specific cellular pathways that are important in cancer cells, while causing minimal damage to normal cells. The Company's most advanced product candidate, rigosertib, is a small molecule inhibitor of cellular signaling and acts as a RAS mimetic. These effects of rigosertib appear to be mediated by direct binding of the compound to the RAS-binding domain (RBD) found in many RAS effector proteins, including the Raf and PI3 kinases. Rigosertib is protected by issued patents (earliest expiry in 2026) and has been awarded Orphan Designation for MDS in the United States, Europe and Japan. In addition to rigosertib, two other candidates are in the clinical stage, and several candidates are in pre-clinical stages. Onconova.com.

## About INSPIRE

The International Study of Phase III IV Rigosertib, or INSPIRE, is based on guidance received from the U.S. Food and Drug Administration and European Medicines Agency and derives from the findings of the ONTIME Phase 3 trial. INSPIRE is a multi-center, randomized controlled study to assess the efficacy and safety of IV rigosertib in HR-MDS patients who had progressed on, failed to respond to, or relapsed after previous treatment with an HMA within the first nine months of initiation of HMA treatment. This time frame optimizes the opportunity to respond to treatment with an HMA prior to declaring treatment failure, as per NCCN Guidelines. The trial will enroll approximately 225 patients randomized at a 2:1 ratio into two treatment arms: IV rigosertib plus Best Supportive Care versus Physician's Choice plus Best Supportive Care. The primary endpoint of INSPIRE is overall survival and an interim analysis is anticipated. Full details of the INSPIRE trial, such as inclusion and exclusion criteria, as well as secondary endpoints, can be found on [clinicaltrials.gov](http://clinicaltrials.gov) (NCT02562443).



## Contact

Ajay Tandon  
SeeThruEquity  
[www.seethruequity.com](http://www.seethruequity.com)  
(646) 495-0939  
[info@seethruequity.com](mailto:info@seethruequity.com)

## Disclosure

This research report has been prepared and distributed by SeeThruEquity, LLC ("SeeThruEquity") for informational purposes only and does not constitute an offer, solicitation or recommendation to acquire or dispose of any investment or to engage in any transaction. This report is based solely on publicly-available information about the company featured in this report which SeeThruEquity considers reliable, but SeeThruEquity does not represent it is accurate or complete, and it should not be relied upon as such. All information contained in this report is subject to change without notice. This report does not constitute a personal trading recommendation or take into account the particular investment objectives, financial situation or needs of an individual reader of this report, and does not provide all of the key elements for any reader to make an investment decision. Readers should consider whether any information in this report is suitable for their particular circumstances and, if appropriate, seek professional advice, including tax advice. This report contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties, many of which are beyond the company's control. Actual results could differ materially and adversely from those anticipated in such forward-looking statements as a result of certain industry, economic, regulatory or other factors.

SeeThruEquity is not a FINRA registered broker-dealer or investment adviser and does not provide investment banking services. SeeThruEquity does not accept or receive fees or other compensation for preparing its research reports. SeeThruEquity has not been retained or hired by the company featured herein or by any other party to prepare this report.

In some but not in all instances, SeeThruEquity and/or its officers, directors or affiliates may receive compensation from companies featured in its reports for non report-related services which may include charges for presenting at SeeThruEquity investor conferences, distributing press releases and performing certain other ancillary services. The company featured in this report paid SeeThruEquity its standard fee described below for distributing a press release on this report. Such compensation is received on the basis of a fixed fee and made without regard to the opinions and conclusions in its research reports. The fee to present at SeeThruEquity conferences is no more than seven thousand dollars, and the fee for distributing press releases is no more than fifteen hundred dollars. The fees for performing certain other ancillary services vary depending on the company and service provided but generally do not exceed five thousand dollars. In no event is a company on which SeeThruEquity has issued a report required to engage it with respect to these non report-related services. SeeThruEquity and/or its affiliates may have a long equity position with respect to a non-controlling interest in the publicly traded shares of companies featured in its reports, and follows customary internal trading restrictions pending the release of its reports.

SeeThruEquity's professionals may provide verbal or written market commentary that reflects opinions that are contrary to the opinions expressed in this report. This report and any such commentary belong to SeeThruEquity and are not attributable to the company featured in its reports or other communications. The price and value of a company's shares referred to in this report may fluctuate. Past performance by one company is not indicative of future results by that company or of any other company covered by a report prepared by SeeThruEquity. This report is being disseminated primarily electronically and, in some cases, in printed form. An electronic report is made simultaneously available to all recipients. The information contained in this report is not incorporated into the contents of our website and should be read independently thereof. Please refer to the Disclosures section of our website for additional details.

Copyright 2011-2017 SeeThruEquity, LLC. No part of this material may be (i) copied, photocopied or duplicated in any form or by any means or (ii) redistributed without the prior written consent of SeeThruEquity, LLC.